

GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS ON MENTORED CLINICAL SCIENTIST DEVELOPMENT AWARD IN ANESTHESIOLOGY, CLINICAL PHARMACOLOGY, AND TRAUMA AND BURN INJURY (K08) APPLICATIONS

NIGMS PAR-98-084

Complete details at: <http://grants.nih.gov/grants/guide/pa-files/ PAR-98-084.html>

The National Institute of General Medical Sciences (NIGMS) will accept applications for the Mentored Clinical Scientist Development Award (MCSDA)(K08) in the areas of anesthesiology, clinical pharmacology, and trauma and burn injury research.

NIGMS is offering the K08 award to support the development of outstanding academic physician scientists. This mechanism provides support for a period of supervised research and study for clinically trained professionals who have the commitment and the potential to develop into productive, independent investigators. The award period will last three, four, or five years and must include a plan to obtain and integrate a fundamental and theoretical understanding of the chosen field with a period of intensive laboratory or clinically oriented research. The proposed research should have both intrinsic importance and be a suitable vehicle for learning the skills necessary to become an independent researcher. The scope and nature of the proposed research should also be suitable for potential development into an independently funded research endeavor.

This award will support developmental experiences in either laboratory or clinical research. Because of the focus on a progression to independence as a researcher, the prospective candidate for the K08 award should propose a period of development consistent with this goal and his or her previous research and clinical experience. For example, a candidate with limited experience in a given field of research may find a phased developmental program lasting for five years, that includes a designated period of didactic training and closely supervised research experience, the most efficient means of attaining independence. A candidate with substantial previous research experience may require a shorter award period appropriate for the transition to independence. In all cases, the candidate must provide evidence of attainment of a broad understanding of theoretical aspects of the relevant basic or clinical science, or s/he will attain the same during the course of this award.

General considerations in reviewing these applications:

- The candidate must have an M.D. degree or its equivalent
- Must have completed postgraduate clinical training and have secured a faculty appointment in an appropriate research-intensive environment
- Must identify a mentor with extensive research experience
- Must be willing to spend a minimum of 75 percent of full-time professional effort conducting research and research career development
- Applications may be submitted, on behalf of candidates, by domestic, non-Federal organizations, public or private, such as medical schools

CRITIQUE

Each major review element within the Mentored Clinical Scientist Development Award In Anesthesiology, Clinical Pharmacology, and Trauma and Burn Injury application (Candidate, Career Development Plan, Research Plan, Mentor, Environment, and Budget) should be commented on in a separate section of your written critique. For revised applications, also comment briefly on whether the application is improved, the same, or worse. In addition, provide a one-sentence summary of your evaluation at the end of each section. After considering all of the review criteria, briefly summarize the strengths and weaknesses of the application and recommend an overall level of merit in a section titled Summary and Recommendations (see below). Please note that your comments will be used essentially unedited in the final summary statement sent to the candidate.

The following review criteria will be applied:

Candidate

- Quality of the candidate's academic and clinical record
- Potential to develop as an independent clinical or laboratory based researcher
- Commitment to a research career

Career Development Plan

- Likelihood that the career development plan will contribute substantially to the scientific development of the candidate
- Probability of development of a competitive independent research program
- Appropriateness of the content and duration of the proposed didactic and research phases of the award
- Consistency of the career development plan with the candidate's career goals and prior research experience
- Quality of the proposed training in responsible conduct of research

Research Plan

Reviewers recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced investigator. Although it is understood that K08 applications do not require the level of detail necessary in regular research grant proposals, a fundamentally sound research plan must be provided. In general, less detail is expected with regard to research planned for the later years of the award, but the application should outline the general goals for these years. The following details should be provided:

The significance of the area of research in which the candidate proposes to establish independence:

- Appropriateness of the research plan to the stage of research development and as a vehicle for developing the research skills as described in the career development plan
- Scientific and technical merit of the research question, design and methodology

- Relevance of the proposed research to the candidate's career objectives
- Adequacy of the plan's attention to gender and minority issues associated with projects involving human subjects

Mentor

- Appropriateness of mentor's research qualifications
- Quality and extent of mentor's proposed role in providing guidance and advice to the candidate
- Previous experience in fostering the development of researchers
- History of research productivity and support

Environment

- Applicant institution's commitment to the scientific development of the candidate and assurances that the institution intends the candidate to be an integral part of its research program
- Adequacy of research facilities and the availability of appropriate educational opportunities
- Quality and relevance of the environment for scientific and professional development of the candidate
- Applicant institution's commitment to an appropriate balance of research and clinical responsibilities.

Budget

- Justification of the requested budget in relation to career development goals and research aims

SUMMARY AND RECOMMENDATION

In one paragraph, briefly summarize the most important points of the Critique, addressing the strengths and weaknesses of the application in terms of the six review criteria. An application does not need to be strong in all categories to receive a good rating. Each scored application will receive a numerical rating that will reflect your opinion of its merit. The numerical rating is based on a scale from 1.0 for the most meritorious to 5.0 for the least meritorious with increments of 0.1 unit. Reviewers should score the "average" application they customarily review in their Scientific Review Group with a score of 3.0. This practice is designed to have 3.0 be the median.

OTHER CONSIDERATIONS

Foreign Training: In a separate section, describe the scientific advantages of the proposed training in a foreign country and compare it to relevant training opportunities available in this country. Comment on any special talents, resources, populations, or environmental conditions that are not readily available in the United States or that augment existing resources. This consideration should not be factored into your overall recommendation and rating.

Protection Of Human Subjects From Research Risks: Evaluate the application with reference to the following criteria: risk to subjects, adequacy of protection against risks, potential benefit to the subjects and to others, importance of the knowledge to be gained. (If the applicant fails to address **all** of these elements, notify the SRA immediately to determine if the application should be withdrawn.) If all of the criteria are adequately addressed, and there are no concerns. Write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable. If one or more criteria are inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. If the application indicates that the proposed human subjects research is exempt from coverage by the regulations, determine if adequate justification is provided. If the claimed exemption is not justified, indicate "Unacceptable" and explain why you reached this conclusion. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRA immediately to determine if the application should be withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

Gender, Minority And Children Subjects: Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them. Each project involving human subjects must be assigned a code using the categories "1" to "5" below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (no U.S. subjects). If the study uses both then use codes 1 thru 4. Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded "U".

Category	Gender (G)	Minority (M)	Children (C)
1	Both Genders	Minority & non-minority	Children & adults
2	Only Women	Only minority	Only children
3	Only Men	Only non-minority	No children included
4	Gender Unknown	Minority representation unknown	Representation of children unknown
5		Only Foreign Subjects	

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under the "Research Plan" section of the critique, and should be factored into the score as appropriate.

Animal Welfare: Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

Biohazards: Note any materials or procedures that are potentially hazardous to research personnel and indicate whether the protection proposed will be adequate.

Further information about NIH research training and career development opportunities can be found at <http://grants.nih.gov/training>